

DEPARTMENT OF DISABILITIES, AGING AND INDEPENDENT LIVING

Division of Licensing and Protection
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April 27, 2015

Dr. John Brumsted, Administrator University Of Vermont Medical Center 111 Colchester Ave Burlington, VT 05401

Provider ID #: 470003

Dear Dr. Brumsted:

The Division of Licensing and Protection completed a survey at your facility on March 19, 2015. The purpose of the survey was to determine if your facility met the conditions of participation for Acute Care Hospitals found in 42 CFR Part 482.

Following the survey, your facility submitted a Plan of Corrections (POC) which was found to be acceptable on April 8, 2015.

Sincerely,

Suzanne Leavitt, RN, MS

Assistant Division Director

Segune E. Louth Ru, ms

Director State Survey Agency

Enclosure



V 000 INITIAL COMMENTS

An unannounced on-site complaint investigation was conducted by the Division of Licensing and Protection from 3/16/15 through 3/19/15 to determine compliance with Condition of Participation for: Patient Rights; Nursing Services, Quality Assurances/Performances Improvement, Medical Staff, Governing Body, Pharmaceutical Services and Anesthesia Services for Complaint# 00013152. The following regulatory violations were identified:

Based on information gathered, the hospital was determined not to be in compliance with Conditions of Participation for: Patient Rights and Quality Assessment Performance Improvement, Pharmaceutical Services and Nursing Services. Based on information gathered at the time of survey, an Immediate Jeopardy situation was determined to exist based on the hospital's failure to initiate immediate action after a significant medication error was committed.

The Conditions of Participation for Nursing Services, Patient Rights, Quality Assessment/Performance Improvement and Pharmaceutical Services were not met.

Note: The Immediate Jeopardy was removed by the hospital on 3/1B/15 at 5:05 PM when a plan to correct the Immediate Jeopardy was accepted.

PLAN OF CORRECTION

A 115 482.13 PATIENT RIGHTS

A hospital must protect and promote each patient's rights.

This CONDITION is not met as evidenced by:

Based on staff interview and record review the Condition of Participation: Patient Rights was not met as evidenced by the hospital's failure to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient.



Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

• An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

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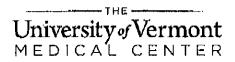
PLAN OF CORRECTION

A 144 482.13(c)(2) PATIENT RIGHTS: GARE IN SAFE SETTING

The patient has the right to receive care in a safe setting.

This STANDARD is not met as evidenced by: Based on staff interview and record review the hospital failed to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient, (Patient #1) Findings include:

Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BiPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it was determined the patient required



admission.

Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory, Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI (a standard of care in emergency airway management for intubations not anticipated to be difficult when medications are administered simultaneously to render a patient unconscious to facilitate endotracheal intubation).

For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg). Both medications were ordered to be administered IV (Intravenously) Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #i. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 document: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped."

Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought l only had IDO mg, in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care.

The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 11:22 AM, MICU Nurse #2 stated when a physician gives a verbal order



for a medication during an intubation or cardiac arrest s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipation that they physician might order sequential doses.

Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is"... you draw up what the order is and that is what is expected ... " of nurses.

In addition, although a Root Cause Analysis

(RCA) was developed on 1/29/15 and 3 action plans were formulated to improve patient safety and nursing practice, as of 3/17/15 none of the plans had been initiated. It was not until an Immediate Jeopardy was determined to exist on 3/18/15 the hospital took immediate corrective action to ensure patient safety by replacing Ketamine 500 mg multidose vials with 200 mg, vials in all RCI medication kits; Nursing Services received direction regarding drawing up only the dose ordered by providers and a review of "read back" process was reinforced.

Refer to Tags: A-0286; 0405 & 500

Action Plan

- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result of this review, the improvement plans were approved for implementation.
- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as of 4/3/2015.
- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.
- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the

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University of Vermont Medical Center <u>Sentinel/Serious Adverse Event Process Flow</u> to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/2015. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.

- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication. The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.
- An educational curriculum that supports practices outlined in the revised MODAR policy was developed by the Directors of Nursing. The Vice President of Nursing communicated the expectation that all scheduled staff is required to complete the curriculum which includes a tutorial and scenario based competency assessment by 4/16/2015. In addition to this education, related content will be added to new nursing orientation effective 4/16/2015.
- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).
- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.
- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.

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- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.
- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product, a change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.
- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the policy revisions effective 4/3/2015.
- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.
- Kit contents will be managed and monitored through the "KitCheck" system. This
 system allows for medication tracking of lot number and kit accuracy through the use
 of radiofrequency identification tags.

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PLAN OF CORRECTION

A 263 482.21 QAPI

The hospital must develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.

The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

This CONDITION is not met as evidenced by: The Condition of Participation: Quality Assurance and Performance Improvement (QNPI) was not met as evidenced by the failure of the hospital to implement an effective hospital-wide action plan after a significant adverse patient event had occurred.

Refer to Tag -A- 0286, 0405 & 500

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

• An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.



PLAN OF CORRECTION

A 286 482.21 (a), (c)(2), (e)(3) PATIENT SAFETY

- (a) Standard: Program Scope
- (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will ... identify and reduce medical errors.
- (2) The hospital must measure, analyze, and track ... adverse patient events ...
- (c) Program Activities
- (2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.
- (e) Executive Responsibilities, The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:...
- (3) That clear expectations for safety are established.

This STANDARD is not met as evidenced by: Based on staff interview and record review there was a failure of Quality Assurance/Performance Improvement to effectively evaluate, fully analyze and fully implement immediate actions when a significant adverse patient event occurred. (Patient #1) Findings include:

On 1/27/15 Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and in respiratory distress.

Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation

as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory

Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI to secure an airway for Patient #1.

For the emergent intubation the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20

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minutes for correct dosing of 1 to 2 mg/kg) Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 10D mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 1 DO mg. amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx. 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse. Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of Ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcomeI could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped," Shortly after the incident a "Safe Report" was filed (Adverse Event Report) and on 1/29/15 a Root Cause Analysis (RCA) was conducted which included staff involved in the event on 1/27/15 along with the Director tor Critical Care, Medication Safety Coordinator, Director of Critical Care Nursing and a ONPI consultant.

Per interview on 3/16/15 at "12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the Resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial throughout the hospital. This would provide a safety barrier in preventing to larger of a dose of Ketamine being drawn and administered during a RCI noting Nurse #"1 had drawn and administered a dose greater then what was prescribed. The Director confirmed, although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the RGI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require.

A second action plan was to developed policy practice guidelines for administering medications noting that Nurse # 1 had drawn up a larger dose of Ketamine, deviating from the physician order. Per interview with Nurse #1 on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time

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of the RSI s/he had anticipated Patient #1 would require more Ketamine due to the patient's weight so s/he decided to draw up more then what the physician had ordered. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. in the syringe". Nurse #1 stated the practice of drawing more medication then ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care. Deviating from the physician's order during an emergent procedure was confirmed by the Nurse Manager of MICU on 1/17/15 at 9:45 AM as still presently going on with some nurses practicing in MICU.

A third action plan was reinforcing the "closed loop communication" process between physicians and the nurse during emergent procedures. The Director of Patient Safety and Quality confirmed Nurse #1 did repeat back to the physician what the verbal order was (Ketamine 100 mg) and acknowledged 100 mg, of Ketamine was being administered, however Nurse #1 pushed intravenously 500 mg.

When determining what had been enacted upon of the 3 areas identified from the RCA, it was confirmed multidose vials of Ketamine 100 mg/Sec still remained in all of the RCI medication boxes throughout the hospital. Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services.

A hospital wide education of nurses reinforcing standards of nursing practice regarding following physician orders and not drawing up more medication then what was ordered had not been addressed. Although the MICU Nursing Council meeting on 2/20/15 discussed the event of 1/27/15 there was a failure to implement a hospital wide directive to nurses regarding drawing up only what the physician has ordered. In addition, it was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 the nursing practice of drawing up more medication then what was ordered during an emergent procedure was probably still being performed by some nurses in MICU.

In regards to the "close loop communication", the Medical Director of Adult Critical Care Services confirmed on 3/18/15 at 10:15 AM although s/he has brought the incident to the attention of physicians practicing in MICU, reminding them to continue close communication practice with nurses involved during emergent procedures, s/he failed to share the incident and concerns with Surgical Intensive Care Unit (ICU) or to other directors who provide supervision where Ketamine may be used during RC1.

It was not until an Immediate Jeopardy situation was determined to exist, when the hospital made the necessary changes to assure care was provided in a safe setting. The multidose vials of 500 mg of



Ketamine were exchanged for 200 mg vials in all RCI medication boxes. Under the Direction of the VP of Nursing Services the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and deployed throughout all nursing services. In addition, the module reinforced the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider.

Action Plan

- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result of this review, the improvement plans were approved for implementation.
- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as of 4/3/2015.
- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.
- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the University of Vermont Medical Center Sentinel/Serious Adverse Event Process Flow to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/15. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.
- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication.

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The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.

- An educational curriculum that supports practices outlined in the revised MODAR
 policy was developed by the Directors of Nursing. The Vice President of Nursing
 communicated the expectation that all scheduled staff is required to complete the
 curriculum which includes a tutorial and scenario based competency assessment by
 4/16/2015. In addition to this education, related content will be added to new nursing
 orientation effective 4/16/2015.
- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).
- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.
- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.
- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.
- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product, a change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy



technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.

- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the policy revisions on 4/3/2015.
- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.
- Kit contents will be managed and monitored through the "KitCheck" system. This
 system allows for medication tracking of lot number and kit accuracy through the use
 of radiofrequency identification tags.

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PLAN OF CORRECTION

A385 482.23 NURSING SERVICES

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The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

This CONDITION is not met as evidenced by: Based on staff interview and record review, the Condition of Participation: Nursing Services was not met based on hospital nursing staff's failure to follow physician orders for the administration of an intravenous medication and administering a dose greater then what was ordered.

Refer to TAG: A- 0405

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

• An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.



PLAN OF CORRECTION

A405 482.23(c)(1), (c)(1)(i) & (c)(2) ADMINISTRATION OF DRUGS

- (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.
- (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482,.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.
- (2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

This STANDARD is not met as evidenced by: Based on staff interview and record review, a Registered Nurse (RN) fatled to prepare and administer a medication in accordance with the orders of the practitioner responsible for the patient's care and in accordance with hospital policy and standards of nursing practice for 1 of 10 applicable patients. (Patient #1) Findings include:

Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BiPAP (Biphasic positive airway pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonary edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Patient #1 was evaluated by Critical Care physicians and it was determined the patient required admission.

Per Progress Note, Patient #1 was transferred from the ED to the Medical Intensive Care Unit (MICU) at 4:20 PM. During the process of transferring the patient from the ED stretcher to the MICU bed, Patient #1 became obtunded (altered level of consciousness) and was in respiratory distress. Critical Care physicians rapidly responded and it was determined at approximately 4:25 PM Patient #1 required intubation for mechanical ventilation as a result of respiratory distress/compromise. Nursing staff obtained and brought to the patient's room the Rapid Sequence Intubation (RSI) medication box. Meanwhile Respiratory Therapists and physicians prepared intubation instruments and endotracheal tube for the RSI.

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For the emergent intubation, the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg {an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg). Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 100 mg, amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650 - 1655 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenly given a significantly larger dose of his/her induction agent of ketamine than I had ordered. I stated that Ketamine is ideally the agent we use for patients with cardiogenic shock or hemodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than I had ordered and was concerned that it may have contributed to his/her poor outcome. Could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped."

Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/he had thought Patient #1 may require increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought I only had 100 mg, in the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care.

The nursing practice of drawing up more medication then what was ordered was further confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 1:22 AM, MICU Nurse #2 stated when a physician gives a verbal order for a medication. During an intubation or cardiac arrest, s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the



syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at times, s/he would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when s/he would draw up more medication in the syringe in anticipation that the Physician might order sequential doses. However, per interview on 3/18/15 at 10:15 AM the Medical Director of Adult Critical Care Services acknowledged the drawing up of more medication by nurses then what the physician has ordered during an emergency procedure creates "...a potential for error".

Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is"--- you draw up what the order is and that is what is expected ..." of nurses. Per hospital policy Intravenous Medications; Preparation and Administration of: by RNs and LPNs published on 7/29/14 states" 3. A RN will administer medications via 1V push as ordered by a physician and dispensed by the pharmacy."

Action Plan

- The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy was revised to include specific language regarding medication preparation and administration in emergency situations. Articulated in this policy were accompanying nursing and physician practice expectations including the expectations related to preparation of the ordered dose. Clearly articulated in the referenced policy is the requirement for closed loop (repeat back) communication with the physician before administering the medication. The MODAR policy was approved by the Directors of Nursing, the Director of Pharmacy and the Physician Chair of the Pharmacy and Therapeutics Committee on 4/1/2015.
- An educational curriculum that supports practices outlined in the revised MODAR
 policy was developed by the Directors of Nursing. The Vice President of Nursing
 communicated the expectation that all scheduled staff is required to complete the
 curriculum which includes a tutorial and scenario based competency assessment by
 4/16/2015. In addition to this education, related content will be added to new nursing
 orientation effective 4/16/2015.
- The survey response action plans were reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC) on 3/30/15. This meeting is comprised of the Physician Chairs of each healthcare service, Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC).



- The Chief Medical Officer communicated the medication practice expectations during an emergency event as outlined in the Medication Order, Delivery, Administration and Recording policy (MODAR) to the medical staff. Key points highlighted were: the medication preparation of the ordered dose and accompanying closed loop communication (repeat back the order, and verify that the medication, dose and route were heard correctly) prior to administration. This was completed on 4/6/2015.
- Our performance in accordance with The University of Vermont Medical Center Medication Order, Delivery, Administration and Recording (MODAR) policy specific emergency medication preparation and administration will be monitored through our internal mock survey process. Performance feedback will be provided directly to staff/clinicians. In addition, data will be provided to Nursing Leadership and the Chief Medical Officer for any required follow-up action.

 Procedure 4.7.46

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PLAN OF CORRECTION

A 490 482.25 PHARMACEUTICAL SERVICES

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

This CONDITION is not met as evidenced by: The Condition of Participation: Pharmacy Services was not met due to the failure of Pharmacy Services to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital

Action Plan

Please note that we are responding to the Conditional Findings at the Standard Level.

• An immediate jeopardy situation was identified by the state surveyors on 3/18 during a survey conducted on 3/16-3/19. The immediate jeopardy was removed on 3/18 at 5:05 when a plan to correct the immediate jeopardy was submitted and accepted by the surveyor team. This plan was summarized in a letter and read as follows:

As part of our plan for immediate correction of the findings stemming from the survey conducted beginning on March 16th, the following changes have been implemented: On 3/18/15, under the direction of the Vice President of Nursing the standard of practice related to the administration of medications from a vial or ampule was reviewed and an educational module was developed and will be deployed by 1630 on 3/18/15. The module reinforces the practice of drawing up only

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the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. All nursing staff will be required to attest that they have completed the educational module prior to the delivery of patient care. In addition, the 500mg ketamine vials located in the intubation kits in the PYXIS machines will be replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change will be completed by 2000 on 3/18/15.

PLAN OF CORRECTION

A 500 482.25(b) DELIVERY OF DRUGS

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

This STANDARD is not met as evidenced by: Based on observations, interview and record review the Pharmacy Services failed to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital. (Patient #1) Findings include:

During an emergent intubation of a patient in MICU on 1/27/15 the physician directed via verbal orders specific medications to be prepared by nursing which included Rocuronium 100mg (a neuromuscular blocker which provides skeletal muscle relaxation). The physician also ordered Ketamine100 mg (an anesthetic agent used for sedation/analgesic effect with a time to effect of 45 seconds to 60 seconds and duration of 10-20 minutes for correct dosing of 1 to 2 mg/kg). Both medications were ordered to be administered IV (Intravenously). Nurse #1, assigned to Patient #1 at the time of admission to MICU, documented s/he administered. Rocuronium 100 mg at 4:46 PM followed by Ketamine. Although the physician had ordered Ketamine 10D mg. amounting to 1 cc of medication, Nurse #1 drew up the total amount of the multidose vial of 5cc/500 mg of Ketamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was in cardiac arrest with Pulseless Electrical Activity (PEA) and chest compressions were started. Per Progress Note, Nurse #1 documents: "At approx 1650- 1655 (4:50- 4:55 PM), realization of overdose of ketamine realized and MD XXXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was pronounced dead at 5:16 PM.

Per interview on 3/16/15 at 12:50 PM, the Director of Patient Safety and Advocacy stated issues identified during the RCA included the size and concentration of the multidose vial of Ketamine used by Nurse #1. An action plan included the resuscitation Committee which included pharmacy would evaluate alternative concentrations of Ketamine such as 100 mg or 200 mg vials and standardize the dose vial _ throughout the hospital. This would provide a safety barrier in preventing a larger dose of Ketamine being drawn and administered during a RGI, noting Nurse #1 had drawn and administered a dose greater then what was prescribed. The Director confirmed although it had been 49 days since the death of Patient #1, changes had not been made to remove the 500 mg. multidose vials of Ketamine from the

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RGI medication boxes, in exchange for a reduced concentration. The Director stated one reason preventing the change was due to a Ketamine drug shortage and Anesthesia still needed to be consulted regarding the specific concentrations they require. Per observation in MICU on 3/17/15 at 8:40 AM, the RGI medication boxes still contained Ketamine 100 mg/5 cc multidose vials.

Per interview on 3/16/15 at 4:10 PM a pharmacist who is the medication safety coordinator confirmed s/he was involved with the RCA and was working on an action plan to replace the multidose vials of 500 mg of Ketamine. "We are pretty close to the result of having a 10 mg/ml vial and 20 cc vial (200 mg)" and further noting the ICUs never use more than 200 mg of Ketamine during an event. The pharmacist also acknowledged a shortage of Ketamine and that further discussions with Anesthesia Services was needed prior to making any changes in Ketamine concentration. The pharmacist further acknowledged proper medication administration is looking at the vial and making sure you have the right dose.

Per interview on 3/17/15 at 1:00 PM, the Chief of Anesthesiology acknowledged Anesthesia Services has 2 concentrations of Ketamine, 10 mg/1 cc and 100 mg/1 cc available for the provision of patient care. The Chief of Anesthesiology stated several years ago his/her service requested pharmacy to provide predrawn syringes of Ketamine, very low doses of Ketamine 0.1 and 0.2 mg/kg used as an adjunct to reduce opioid dosing. Anesthesia Services does have access to Ketamine 100 mg/1 cc in Pyxis (automated medication station) but there are alerts to assure the right dose is being used.

Per interview on 3/19/15 at 12:15 PM the Pharmacy Manager for Clinical Practice confirmed there was a drug shortage of Ketamine in December of 2009 and was resolved in 2010. The Manager further confirmed if asked in January 2015 to make a change in Ketamine vial concentrations, various drug concentrations were and still are available. Further confirming Anesthesia Services already has the Pharmacy department providing predawn syringes of Ketamine for specific needs within Anesthesia services. On 3/19/15 12:10 PM, the Pharmacy Manager for Clinical Practice confirmed Ketamine 500 mg mutidose vials had been removed from all the RCI boxes and replaced with 200 mg Ketamine vials.

Action Plan

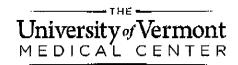
- The plan of correction for each survey deficiency was reviewed by the Vice President of Quality and Operational Effectiveness with the members of the Academic Medical Center Committee (AMC). This meeting is comprised of the Physician Chairs of each healthcare service, the Vice Presidents and Executive Leadership of the University of Vermont Medical Center (UVMMC). As a result, the plans were approved for implementation.
- A motion that all Root Cause Analysis and accompanying action plans be presented for review at the AMC biweekly meeting was approved by the Committee membership and is in effect as 4/3/2015.
- Effective immediately, the accountable leader(s) will report Root Cause Analysis action plans and accompanying timelines at the Weekly Operations Committee comprised of the Vice Presidents and Executive Leadership of UVMMC.
- Effective immediately, a status update of the Root Cause Analysis action plan with its' accompanying timeline will be provided at the next scheduled monthly Patient

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Safety Event Review Subcommittee (PSERS) by the accountable Leaders. The update is in addition to the already existing 3, 6 and 12 month root cause analysis reporting now going to PSERS. The Director of Patient Safety and Advocacy updated the University of Vermont Medical Center Sentinel/Serious Adverse Event Process Flow to reflect the new reporting requirements. The changes were approved by the Chief Medical Officer on 3/31/15. The changes to the Process Flow were communicated to the Vice Presidents and Directors on 3/31/2015 by the Director of Patient Safety and Advocacy.

- The 500 mg ketamine vials located in the intubation kits in the PYXIS machines were replaced with 200 mg vials of ketamine by the Manager of Pharmacy Clinical Practice. This change was completed by 2000 on 3/18/15. The ketamine 500 mg vials were also replaced with ketamine 200 mg vials in the intubation boxes in all code carts. This change was completed on 3/19/2015.
- Revisions were made to The University of Vermont Medical Center Drug Recall and Shortage policy to include the following: when a drug shortage necessitates the substitution of the form, concentration, or size of a product available to meet clinical needs, a notation of the substitution will be entered into the internal pharmacy shortage website. Notated products will be reviewed weekly and when there are adequate supplies of the original product the change will be made. This policy was approved by the Director of Pharmacy on 4/1/2015. The pharmacists and pharmacy technicians involved in shortage management have reviewed the Drug Recall and Shortage Policy effective 4/1/15.
- The Manager of Pharmacy Clinical Practice revised the University of Vermont Medical Center Resuscitation Policies to include an appendix that outlines the code cart contents. Any changes to the code cart contents will require approval by the Resuscitation Committee. The Resuscitation Committee approved the respective policy revisions effective 4/3/2015.
- The Manager of Pharmacy Clinical Practice in collaboration with the Director of Pharmacy formalized the medication kit management processes by creating the University of Vermont Medication Storage Kit Procedure. The referenced procedure articulates that medications contained in emergency medication kits will be reviewed for appropriateness according to published guidelines such as ACLS. In addition, medications will be supplied in the most ready to administer form and size dose to meet most patient needs. This was approved by the Director of Pharmacy on 4/1/2015.
- Kit contents will be managed and monitored through the "KitCheck" system. This system allows for medication tracking of lot number and kit accuracy through the use of radiofrequency identification tags.

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April 2, 2015

J. William Roberson
Associate Regional Administrator
Northeast Division, Survey & Certification
Department of Health and Human Services
Centers for Medicaire and Medicaid Services
JKF Federal Building, Government Center
Room 2325
Boston, MA 02203

Re:

CMS Certification Number: 470003 Survey ID: 9HZ611, 03/19/2015 Initial Notice of Termination

Dear Mr. Roberson,

I am submitting Form CMS -2567 and the attached Plan of Correction in response to the Statement of Deficiencies from the survey completed by the State of Vermont Division of Licensing and Protection on March 19, 2015.

The University of Vermont Medical Center is committed to continuously improving the quality of care and services we provide to our patients. As part of our ongoing performance improvement efforts I have attached our response to the regulatory deficiencies cited.

If you have any questions regarding the attached Plan of Correction or require further clarification, please do not hesitate to contact me.

Sincerely,

Anna Noonan

Vice President, Jeffords Institute for Quality The University of Vermont Medical Center

111 Colchester Avenue Burlington, Vermont 05401

Phone: 802-847-4970 Fax: 802-847-6274

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Any deficiency statement ending with an astansk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other eafsguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following lits date of survey whether or not a plan of correction is provided. For nursing homes, the share findings and plants of correction are discloseble 14 days following the date these documents are made evaluable to the facility. It delictorates are cited, an approved plan of correction is requisite to continued program participation.

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PRINTED: 03/24/2016 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED CENTERS FOR MEDICARE & MEDICAID SERVICES MB NO, 0838-039<u>1</u> STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (XI) PROVIDER/BUPPLIER/CLIA (DENTIFICATION NUMBER: (XE) MULTIPLE CONSTRUCTION (X8) DATE BURYEY
COMPLETED A. BUILDING C 470003 a. WING 03/19/2015 STREET AUDRESS, CITY, STATE, ZIP COOR NAME OF PROVIDER OR SUPPLIER 111 COLCHESTER AVE UNIVERSITY OF VERMONT MEDICAL CENTER BURLINGTON, VT 05401 PROVIDERS PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE AFFROMICE BUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY ON LBC IDENTIFYING INFORMATION) COMPLETION CATE PREFIX ľACS DEFICIENCY) A 115 Continued From page 1 A 115 Condition of Participation: Patient Righte was not met as evidenced by the hospital's fellure to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical Intensive Care Unit for 1 applicable patient. Refer to Tag: A - 0144 & 286 482.13(c)(2) PATIENT RIGHTS: CARE IN SAFE A 144 A 144 SETTING The patient has the right to receive care in a safe setting. This STANDARD is not met as evidenced by: 4/17/15 Besed on staff interview and record review the CAHUATIA hospital falled to ensure the provision of patient care was safely provided during an emergency procedure conducted in the Medical intensive Care Unit for 1 applicable patient. (Patient #1) Findings include: Per record review, Patient #1 sought treatment in the Emergency Department (ED) on 1/27/15 after experiencing 3 days of shortness of breath with constriction when breathing and complaining of not being able to catch a good breath, especially if attempting to ambulate. At the time of admission to the ED Patient #1, age 55, was hypotensive (low blood pressure) and required the assistance of BIPAP (Biphasic positive sirvey pressure) machine to assist with breathing. A portable chest x-ray taken at 1:03 PM confirmed Patient #1 was experiencing pulmonery edema and possible pneumonia and the patient was administered a diuretic to treat fluid retention and antibiotics for pneumonia. At 3:11 PM, Pallant #1 was evaluated by Critical Care physicians and it

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PAINTED: 03/24/2018 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED OMB NO. 0038-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES (XX) DATE BURYEY (X1) PROVIDER/SUPPLIER/CLIA STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (XS) MULTIPLE CONSTRUCTION COMPLETED A. BUILDING ¢ a. WING 03/19/2015 470003 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 111 COLCHESTER AVE UNIVERSITY OF VERMONT MEDICAL CENTER BURLINGTON, VT 05401 PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE AFPROFRIATE DEPICIENCY) SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PREFIX TAG (EACH DEFICIENCY MUST BE PRECEDED BY FULL REQULATORY OR LOC IDENTIFYING INPORMATION) A 144 Continued From page 3 A 144 of medication, Nurse #1 drew up the total amount of the multidose vial of 500/500 mg of Kelamine and subsequently at 4:46 PM administered the entire contents of the syringe totaling 500 mg to Patient #1. Per "Adult Resuscitation Record", at 4:53 PM Patient #1 was In cardiac arrest with Pulseless Electrical Activity (PEA) and cheet compressions were started. Per Propress Note, Nurse #1 documents: "At approx 1850 - 1855 (4:50 - 4:55 PM), realization of overdose of ketamine realized and MD XXXX notified as well as charge nurse". Patient #1 received additional cardiac drugs, however resuscitation efforts were unsuccessful, the Code procedure efforts were ended and the patient was PLAN OF

CONNECTION pronounced dead at 6:16 PM; 4/17/15 The attending physician's Progress Note for 1/27/15 at 21:15 states: "I was notified by his/her bedside nurse that the patient was mistakenty given a significantly larger dose of his/her Induction agent of ketamine than I had ordered. I stated that Katamine is ideally the agent we use for patients with cardiogenic shock or hamodynamic instability as it has the least effects on his/her hemodynamics and least likely to cause low blood pressure; however, I stated that this dose was higher than) had ordered and was concerned that it may have contributed to his/her poor outcome.....I could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped." Per interview on 3/17/15 at 9:30 AM, Nurse #1 confirmed that on 1/27/15 at the time of the RSI s/ne had thought Patient #1 may require

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increasing doses of Ketamine to achieve the desired effect and therefore drew up more of the drug in the syringe in anticipation that the

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PRINTED: 03/24/2015 FORM APPROVED DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES OMB NO. 0938-0391 STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (XX) DATE SURVEY COMPLETED (X1) PROVIDER/SUPPLIER/GLIA (X2) MULTIPLE CONSTRUCTION IDENTIFICATION NUMBER: A. BUILOING _ C 470003 A. WING 03/19/2016 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE UNIVERSITY OF VERMONT MEDICAL CENTER BURLINGTON, VT 08401 PROVIDER'S PLAN OF CORRECTION (RACH CORRECTIVE ACTION SHOULD BE ORIO99-REFERENCED TO THE APPROPRIATE DEFICIENCY) SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSO IDENTIFYING INFORMATION) (86) NOITEJAMOD EYAĞ (X4) ID PREFIX 1743 PREFIX TAG Continued From page 4 A 144 physician would order more to be administered during the procedure. However, Nurse #1 stated "In the moment, I thought I only had 100 mg. In the syringe". Nurse #1 stated the practice of drawing more medication than ordered by the physician was something s/he has done throughout his/her nursing practice while working in Critical Care. The nursing practice of drawing up more medication then what was ordered was further. confirmed by the Nurse Manager of MICU on 3/17/15 at 9:45 AM noting, a lot of nursing staff 4/17-115 probably draw up more medication than what the physician has ordered, especially during an emergent patient situation. Per interview on 3/17/15 at 11:22 AM, MICU Nurse #2 stated when e physician gives a verbal order for a medication during an intubation or cardiac arrest, s/he would repeat the order back to the physician for confirmation. After preparing the medication a label is applied to the syringe which would state the drug, the amount drawn up in a syringe and the concentration of the drug. Nurse #2 also confirmed, at limes, s/ha would draw up extra medication then what was ordered. The ED Nurse Manager stated, during interview at 3:38 PM on 3/17/15, that although his/her practice, during RSI, was to draw up just the amount of medication ordered by the physician, there might be times when sine would draw up more medication in the syrings in anticipation that they physician might order sequential doses. Per interview on 3/17/15 at 2:05 PM, the Vice President (VP) of Nursing stated s/he was aware

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of the situation regarding the overdose of Ketamine by Nurse #1 in the MICU and had reviewed the Root Cause Analysis but presently

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		AND HUMAN SERVICES			FORM	03/24/2015 APPROVED 0988-0391
STATEMENT	of deficiencies F correction	(XI) PROVIDER/SUPPLIER/GLIA IDENTIFICATION NUMBERS		E CONSTRUCTION	COM	E SUÄVÄY PLETED C
		470003	B, WING		1 '	19/2015
NAME OF P	ROVIDER OR BUPPLIER			TREET ADDRESS, CITY, STATE, ZIP CODE		
UNIVERS	ITY OF VERMONT M	edical center	1	II COLCHESTER AVE URLINGTON, VT 08401		
(X4) ID PREPIX TAG	(BACH DEPICIENC)	TEMENT OF DEFICIENCIES / MUST BE PRECEDED BY PULL SC:)DENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OP CORRECT (EACH COMRECTIVE ACTION 8HOU CROSS-REPERENCEO TO THE APPRO DEFICIENCY)	LDBE	(X5) COMPLETION DATE
A144	had not provided at case. The VP of Nu related to medication order is and that is in addition, although (RCA) was developlans were formula and nursing practic plans had been init immediate Jeopard 3/18/15 the hospital action to ensure particular in all RCI mad received direction dose ordered by proback" process was Rafer to Tags: A-0	ny direction regarding the practice traing also stated the practice cans is " you draw up what the what is expected" of nurses. In a Floot Cause Analysis sed on 1/29/15 and 3 action ted to improve patient safety e, as of 3/17/16 none of the lated. It was not until an it took immediate corrective attent safety by replacing multidose vials with 200 mg. Itication kits; Nursing Services regarding drawing up only the cylders and a review of "read reinforced.	A 144	SEG ATTACHED PLANT OF CONDUTION		414115
A 263	The hospital must maintain an effective data-driven quality improvement program reflective program reflective program reflective program reflective program reflective program arrangement); and to improve the although the hospital must.	erning body must ensure that the complexity of the tion and services; involves all nits and services (including hished under contract or focuses on indicators related outcomes and the prevention	A 263	Covacinos		
	Avingues or ira AV	Librodiam to testes of ower				

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		AND HUMAN SERVICES			FORM	03/24/2015 APPROVED 0938-0391
STATEMENT	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1	e CONSTRUCTION	(X3) DATE	e sufivey Pleyed
		470003	B. WING			C 19/2015
	PROVIDER OR SUPPLIER SITY OF VERMONT M	EDICAL CENTER	t	TREST ADDRESS, CITY, STATE, ZIP CODE 11 COLGHESTER AVE BURLINGTON, VT 05401		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES 1 MUST BE PRECEDED BY FULL 8C IDENTIFYING INFORMATION)	IÓ PRÉPIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROV DEFICIENCY)	IN D,BE PRIATE	COMPLETION DATE
A 263	Continued From pa	gə 6	A 263		•	
	The Condition of P and Performance in met as evidenced b implement an effect	is not met as evidenced by: rerticipation: Quality Assurance mprovement (QA/PI) was not by the failure of the hospital to tive hospital-wide solion plan diverse patient event had				•
A 288	Refer to Tag - A-0; 462,21(a), (c)(2), (e	286, 0405 & 500 5)(3) PATIENT SAFETY	A 286		į	
	to, an ongoing prog improvement in Ind evidence that it will medical errors.	ust include, but not be limited train that shows measurable loaters for which there is Identify and reduce lat measure, analyze, and		SEE ATTACHED PLAN of Convection	1	4/17/15
	track medical error: analyze their cause	nprovement activities must s and adverse patient events, es, and implement preventive nisms that include feedback			•	
	governing body (or who assumes full to for operations of the administrative offici accountable for ens	onsibilities, The hospital's organized group or individual egal authority and responsibility is tospital), medical staff, and lala are responsible and suring the following: actations for safety are				

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		HAND HUMAN SERVICES E & MEDICAID SERVICES		•	FORM.	03/24/2015 APPROVED 1086-0391
STATEMENT	T OF DEFICIENCIES OF CORRECTION	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(XR) MULTIPLE A. BUILOING _	E CONSTRUCTION	COM	SURVEY PLETED
		470003	B. WING		1 7	19/2015
NAME OF	PROVIDER OR GUPPLIER	<u> </u>		reet address. City. State, zip code	.1	
UNIVER:	SITY OF VERMONT M	MEDICAL CENTER		H COLCHESTER AVE URLINGTON, VT 05401		ļ
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEPIGIENCIES OF MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PAEFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	38 C	COMPLETION (AXI)
A 286	Continued From pa	age 7	A 286			•
	Basad on staff inter was a failure of Qualificant to efficient and fully implement algorificant adverse (Patient #1) Finding On 1/27/15 Patient ED to the Medical 4:20 PM. During the patient from the ED Patient #1 became consciousness) and Oritical Care physic was determined at #1 required intubal as a result of respiration box. Michael Care and physical staff obtains the Rapid Semedication box. Michael Se	Int #1 was transferred from the intensive Care Unit (MiCU) at the process of transferring the D stretcher to the MiCU bed, is obtunded (altered level of and in respiratory distress. Iclans rapidly responded and it approximately 4:25 PM Patient ap		SEC ACKED ATT ACKED PLAN OF COMECTION		पात्मा ^ड

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		AND HUMAN SERVICES		· ·	FORM	03/24/2016 APPROVED 0938-0391	
STATEMENT	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		E CONSTRUCTION	(X3) DATE	PLETED	
		470003	B. WING		-	9/2015	
	HOVIDER OR BUPPLIER SITY OF VERMONT M	REDICAL CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 111 COLCHESTER AVE BURLINGTON, VT' 05401				
(X4) ID PREFIX TAG	IEACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SO IDENTIPYING INFORMATION)	PREPIX TAG	PROVIDER'S PLAN OF CORRE (BACH CORRECTIVE ACTION SH CHOSS-REFERENCED TO THE APP DEPICIENCY)	OULD BE	(X6) GUMPLETION DATE	
A 286	(Intravenously). Nut at the time of admission at the time of admission and ordered Ketam of medication, Nursenously of the mult Ketamine and subsadministered the etotaling 500 mg to Resuscitation Rectin cardiac arrest with Progress Note, Nut 1650 - 1665 (4:50 overdose of ketam notified as well as received additional resuscitation effort procedure efforts a pronounced dead. The attending physical procedure alignificant induction agent of atted that Ketami for patients with cause low blood publis dose was high concerned that it report outcome	irse #1, assigned to Patient #1 ssion to MiCU, documented Recuronium 100 mg at 4:46 tamine. Although the physician nine 100 mg, amounting to 1 cose #1 drew up the total idose vial of Sco/S00 mg of sequently at 4:46 PM ntire contents of the syringe Patient #1. Per "Adult ord", at 4:53 PM Patient #1 was ith Pulsaless Electrical Activity ompressions were started. Per rise #1 documents: "At approx - 4:55 PM), realization of the realized and MD XXXX charge nurse". Patient #1 I cardiac drugs, however a were unauccessful, the Code were ended and the patient was		SEG AMACHED PLM OF- CANCETION	•		
	and on 1/29/15 a	Root Cause Analysis (RCA) wa	6	1		t Cons & of 21	

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		AND HUMAN SERVICES 8 MEDICAID SERVICES			. (0938-0391
STATEMENT	OF DEFICIENCIES F CORRECTION	(Xt) PROVIDER/BUPPLIER/OLIA IDENTIFICATION NUMBER:			CONSTRUCTION	, DOM	e SURVEY PLETED
		470003	e, WING	·		1	19/2015
	ROVIDER OF SUPPLIER			. 11	HEET ADDRESS, CITY, STATE, ZIP CODE 1 COLCHESTER AVE URLINGTON, VT 05401		
(X4) ID PREPIX TAG	AS A OUR DESIGNENCY	TEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SCIDENTIFYING INFORMATION)	PHEP TAG		PROVIDERS PLAN OF CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROPRICENCY)	DBE	(X6) COMPLETION DATE
A 296	event on 1/27/15 at Critical Care, Medical Care, Mediconsultant. Per interview on 3/ Director of Patient Issues Identified duand concentration (Ketamine used by Included the Result Included pharmacy concentrations of 200 mg vials and a throughout the hossafety barrier in professione the death of been made to remivals of Ketamine in exchange for a Director stated on was due to a Keta Anesthesia atili ne the specific conce	ige 9 coluded staff involved in the cong with the Director for callon Sefety Coordinator, Care Nursing and a CA/PI 18/15 et 12:50 PM, the Safety and Advocacy stated using the RCA included the size of the multidose vial of Nurse #1. An action plan sotation Committee which would evaluate alternative (etamine such as 100 mg or tandardize the dose vial eventing to larger of a dose of awn and administered during a #1 had drawn and administered furing a what was prescribed. The I, although it had been 49 days Patiant #1, changes had not nove the 500 mg. multidose from the RCI medication boxss reduced concentration. The e reason preventing the change mine drug shortage end ended to be consulted regarding nitrations they require.		286	ANTACHED PLAN OF		भीत्मार्ड
,	practice guidelines noting that Nurse of Katamine, devis Per interview with AM, Nurse #1 con time of the RSI s/i would require mos	ian was to developed policy is for administering medications #1 had drawn up a larger dose string from the physician order. Nurse #1 on 3/17/15 at 9:30 illumed that on 1/27/15 at the had anticipated Patient #1 re Ketamine due to the patient's cided to draw up more then				•	,

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CENTER	MENT OF HEALTH IS FOR MEDICARE OF DEFICIENCIES F CORRECTION	AND HUMAN SERVICES & MEDICAID SERVICES IX1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			•	FORM. MB NO. (X6) DAY	03/24/2015 APPROVED 0938-0391 2 8URVRY FLETEO
AND PLAND	P COKHBÇTION		A. BUILDIN	10			3
		470003	B. WING.			1 03 <i>f</i>	19/2015
	PROVIDER OR SUPPLIER BYY OF VERMONT M	EDICAL CENTER	-	111	RET ADDRESS, CITY, STATE, ZIP GODS COLCHESTER AVE RUNGTON, VT 05401		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX YAG		PROVIDER'S PLAN OF CORRECTIVE (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROVIDERICLY)	O 86	COMPLETION DATE
A 286	what the physician #1 stated "In the m 100 mg. In the syrin practice of drawing by the physician was throughout his/har in Critical Care. De order during an em confirmed by the N 1/17/15 at 8:45 AM with some nurses purity of the some nurse during Director of Patient Nurse #1 did repet the verbal order 100 administered, how intravenously 500 in the 3 areas iden confirmed multidological modern of the 3 areas iden confirmed in asked change in Ketamir drug concentration.	had ordered, However, Nurse coment, I thought I only had orge". Nurse #1 stated the more medication then ordered as something s/he has done nursing practice while working viating form the physician's tergent procedure was urse Manager of MICU on as still presently going on practicing in MICU. was reinforcing the "closed in" process between physicians are sergent procedures. The Safety and Quality confirmed at back to the physician what the back to the physician what as (Ketamine 100 mg) and mg. of Ketamine was being ever Nurse #1 pushed mg. what had been enacted upon tiffled from the RCA, it was se visis of Ketamine 100 mg. of Ketamine 100 mg. of Micu in all of the RCI madication the hospital. Per interview on the Pharmacy Manager for onfirmed there was a drug in January 2016 to make a se visit concentrations, various as were and still are available. Anssibesia Services aiready department providing predawning for specific needs within		30	SEE ATTACHED PLAN OF Concernor		4 14 15

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DEPART	MENT OF HEALTH	AND HUMAN SERVICES & MEDICAID SERVICES				FORM OMB NO	D: 03/24/2015 MAPPROVED D: 0938-0391
RTATEMENT	OF DEFICIENCIES F CORRECTION	(X1) PROVIDER/SUPPLIER/CUA IDENTIFICATION NUMBER:	(X2) MUL A. BUILC		CONSTRUCTION	()(0) DA	TE SURVEY MPCETED
		470003	B. WING		<u>:</u>		1/19/2015
NAME OF P	ROVIDER OR SUPPLIER				EET ADDRESS, CITY, STAYE, ZIP COI	DE	
UNIVERS	ITY OF VERMONT M	EDICAL CENTER			COLCHESTER AVE RLINGTON, VT 05401		
(X4) ID PAEFIX TAG	(EACH DEPICIENC)	TEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL BC IDZNTIFYING INFORMATION)	ID PREP TAG	ix	PROVIDER'S PLAN OF CORR (PACH CORRECTIVE ACTION & CROSS-REFERENCED TO THE AP DERICHENCY)	HOULD BE	OVIE COMPLETION (XP)
A 286	standards of nursing physician orders ar medication then with addressed. Although meeting on 2/20/15 1/27/16 there was thospital wide direct drawing up only with addition, it was for Manager of MiCU practice of drawing was ordered during probably still being MiCU. In regards to the "of Medical Director of confirmed on 3/18, has brought the imphysicians practice continue close confures involved dusying failed to sharwith Surgical Intendirectors who provided in a safe 500 mg of Ketamina may be standard of practice of medications from the provided and a safe of t	ication of nurses reinforcing ag practice regarding following and not drawing up more plant the MICU Nursing Council is discussed the event of a fallure to implement a live to nurses regarding not the physician has ordered. If the physician has ordered, at the physician has ordered, and energent procedure was performed by some nurses in performed by some nurses in fadult Critical Care Services of Adult Critical Care Services of Adult Critical Care Services of the Incident and concerns used during RCI. Immediate Jeopardy situation of exist, when the hospital made agent to assure care was setting. The mutidose vials of the were exchanged for 200 mg dication boxes. Under the correlated to the administration in a viel or ampule was educational module was educational module was		286	SCE ATTACHED PLAN OF Concerno	:	4k7n)
HOBM ONE	developed and de	played throughout all nursing	B11	· Faoi	my 10: 470003 H o	ontinuation ah	nel Page 12 of 21

PRINTED: 03/24/2015 FORM APPROVED OMB NO. 0938-0391 DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES (X4) DATE SURVEY COMPLETED STATEMENT OF DEPICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/OLIA IDENTIFICATION NUMBER: (X2) MULTIPLE CONSTRUCTION A. BUILOING C 03/19/2015 B. WING 470003 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 111 COLOHESTER AVE UNIVERSITY OF VERMONT MEDICAL CENTER BURLINGTON, VT 05401 PROVIDER'S PLAN OF COARECTION (EACH CORRECTIVE ACTION SHOULD BE CAOSS-REPERENCED TO THE APPROPRIATE DEFICIENCY) SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY ON LSC IDENTIFYING INFORMATION) (MA) DOMPLETION (X4) ID PREFIX PREPIX A 286 A 286 | Continued From page 12 services. In addition, the module reinforced the practice of drawing up only the dose ordered, and the expectation that the "read back" will occur when preparing medications in the presence of and under the direction of the provider. 482.23 NURSING SERVICES A 385 A 385 The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing earvices must be furnished or 56E supervised by a registered nurse. 41715 ATTACHOO This CONDITION is not met as evidenced by: Based on staff interview and record review, the Condition of Participation; Nursing Services was not met based on hospital nureing staff's fallure to follow physician orders for the administration of an intravenous medication and administering a dose greater then what was ordered. Refer to TAG: A- 0405 A 405 482,23(c)(1), (c)(1)(l) & (c)(2) ADMINISTRATION A 405 OF DRUGS (1) Drugs and biologicals must be prepared and edministered in accordance with Federal and 417/15 State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under \$482.12(o), and accepted standards of practice. (i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482,12(a) only if such practitioners are acting in accordance with State iaw, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and

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ATEMPNI	OR DEFICIENCIES	(VI) LIDAMONAGAS A MILITARIA	(X2) MULTIPLE C	ONBTRUCTION	(Xa) DAT QOM	e suavey IPLETED
D PLAN O	CORRECTION	EDMINIONI NEWS	M. BOILDING			C
	!	470003	8. WING	EET ADDRESS, CITY, STATE, ZIP CO		19/2016
	ROVIDER OR SUPPLIER			COLCHESTER AVE		
MIVER	HTY OF VERMONT M	edical center	BU	RLINGTON, VT 05401		nim .
(X4) IO PREFIX TAG	SUMMARY STA (EACH DEFICIENC) REGULATORY OR U	TEMENT OF CEPICIENCIES Y MUST BE PRECEDED BY FULL BC IDENTIFYING INFORMATION	PREFIX PAT TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CAOSS-REFERENCED TO THE A DEFICIENCY)	RECTION SHOULD BE VPPHOPRIATE	OMPLETION DATE
A 405	Continued From pa	age 13	A 405			
, ,	(2) All drugs and b administered by, o or other personnel and State laws and	r under supervision of, norsing in In accordance with Federal I regulations, including g requirements, and in ne approved medical staff				
·	Based on staff init Registered Nurse administer a mediorders of the pracpatient's care and	is not met as evidenced by: erview and record review, a (PN) falled to prepare and cation in accordance with the littlener responsible for the in accordance with hospital rde of nursing practice for 1 of ents. (Patient #1) Findings		SEC ATTALHED PLAN OF Conection	1	4/1211
	the Emergency Dexperiencing 3 disconstriction when not being able to if alternating to a edmission to the hypotensive (low the assistance of pressure) machine portable chest x-Patient #1 was a and possible presentiolities for pressure to antibiotics for phenomena.	r, Patiani #1 sought treatment in epartment (ED) on 1/27/15 after ays of shortness of breath with a breathing and complaining of catch a good breath, especially moulate. At the time of ED Patient #1, age 55, was blood pressure) and required BiPAP (Biphasic positive altware to assist with breathing. A ray taken at 1:03 PM confirmed experiencing pulmonary edema aumonia and the patient was furetic to treat fluid retention and eumonia. At 3:11 PM, Patient #1 y Critical Care physicians and it the patient required admission.	y			Teet Page 14 c

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		AND HUMAN SERVICES & MEDICAID SERVICES				FORM A	09/24/2016 APPROVED 0938-0391
STATEMENT	OF DEFICIENCIES OF CORRECTION	(XI) PROVIDERSUPPLIER/CLIA IDENTIFICATION NUMBER:			E CONSTRUCTION	(X3) DATE COME	SURVEY PLETED
		470003	6. WING	·		03/1	; 19/2015
	PROVIDER OR SUPPLIER SITY OF VERMONT M	BDICAL CENTER		1	TREET ADDRESS, GITY, STATE, ZIP CODE 11 COLCHESTER AVE SURLINGTON, VT 05401		
(X4) ID PREFIX TAG	SUMMARY STA (EACH DEFICIENCY REGULATORY OR L	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IOENTIFYING INFORMATION)	ID PREP TAG	ΙX	PROVIDEN'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REPERENCED TO THE APPROP DEPICIENCY)	18E	COMPLETION CATE
A 405	Per Progress Note, from the ED to the (MICU) at 4:20 PM transferring the pat the MICU bed, Pati (altered level of correspiratory distress rapidly responded approximately 4:25 intubation for mech respiratory distress obtained and broug Rapid Sequence in Meanwhile Respiratory distress obtained and broug Rapid Sequence in Meanwhile Respiratory distress obtained and broug Rapid Sequence in Meanwhile Respiratory distress obtained and brough to the FSI. For the emergent is directed via verbal be prepared by nut Rocuronium 100m which provides skephysiolan also ordered with a time to seconds and durat corract dosing of 1 were ordered to be (intrevenously). Not the time of administered PM followed by Kehad ordered Ketamine and substantine and subst	Patient #1 was transferred Medical Intensive Care Unit During the process of ient from the ED stretcher to ent #1 became obtunded asciousness) and was in Critical Care physicians and it was determined at PM Patient #1 required anical ventilation as a result of /compromise. Nursing staff int to the patient's room the stubation (RSI) medication bex. tory Therapists and physicians instruments and endotracheal instruments and endotracheal orders specific medications to raing which included g (a neuromusoular blocker pietal muscle relaxation). The pred Katamine 100 mg (an sed for sedation/analgesic office of 45 seconds to 60 ion of 10-20 minutes for to 2 mg/ko). Both medications		405	SEE ATTACH ED PLANT OF CANOCITION		411710

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CENTER	MENT OF HEALTH IS FOR MEDICAFIE OF DEFICIENCIES	AND HUMAN SERVICES & MEDICAID SERVICES (K1) PROVIDER/SUPPLIER/CLIA	(X2) MULTIPLE	FOONETBUCTION (XS)	ED: 03/24/2016 RM APPROVED NO. 0938-0391 DATE BURVEY
AND PLAN O	FCORRECTION	IDENTIFICATION HUMBER:			COMPLETED
		470003	8. WING	·]	C 03/19/2015
		470003	1		03/19/2010
	ROYIDER OR SUPPLIER SITY OF VERMONT N		1	TREET ADDRESS, CITY, STATE, ZIP GODE IT COLCHESTER AVE IURLINGTON, VII 05401 ,	•
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A 405	in cardiac arrest W	ith Pulseless Electrical Activity	A 405		
	Progress Note, Nu 1860 - 1856 (4:50 overdose of ketam notified as well as received additional resuscitation effort	ompressions were started. Per rse #1 documents: "At approx - 4:55 PM), realization of line realized and MD XXXX charge nurse". Patient #1 cardiac drugs, however a were unsuccessful, the Code		,	
	pronounced dead The attending physics 1/27/15 at 21:15 st	sician's Progress Note for tates: "I was notified by his/her		SEE	
	given a significant induction agent of stated that Ketami	the patient was mistakenly ly larger dose of his/her ketamine than I had ordered. I ne is ideally the agent we use ardiogenic shock or		PLAY OF	All - 1 -
	hemodynamic inst on his/her hemody cause low blood p this dose was high	ability as it has the least effects mamics and least likely to ressure; however, I stated that her than I had ordered and was		PLAY of	4/17/15
	this dose was higher than I had ordered and was concerned that it may have contributed to his/har poor cutdomeI could not be certain whether it caused his/her cardiac arrest, but I did note that it may not have helped."			Conierror	
	confirmed that on s/he had thought increasing doses desired effect and drug in the syrings physician would of during the proced the moment, if	/17/16 at 9:30 AM, Nurse #1 1/27/15 at the time of the RSI Patient #1 may require of Ketamine to achieve the I therefore drew up more of the in anticipation that the rder more to be administerd ure. However, Nurse #1 stated thought I only had 100 mg. in in #1 stated the practice of		•	
40 Tal 6 Mg.	i drawina mote me	dication than ordered by the nething s/he has done		actity ID: 470053 (f continuetton s	heet Page 18 of 2

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DEPART	MENT OF HEALTH	AND HUMAN SERVICES			FORM APPROVED OMB NO. 0938-0391
		(X2) MULTIPLE CONSTRUCTION A, BUILDING		(X3) OATE BURVEY COMPLETED C	
		s, WING		03/19/2015	
	PROVIDER OR SUPPLIER SITY OF VERMONT M	EDICAL CENTER	111	EET ADDRESS, OITY, STATS, ZIF OODS COLCHESTER AVE RLINGTON, VT 05401	
(X4) IO PREFIX TAG	(하시스) 스탠딩(((디디어)	V MILET OF PRECEDED BY PULL	ID PREFIX TAG	Providens Plan of Correct (Each Corrective action shot Oross-referenced to the Appr Depiciency)	ICD BE I COMPLETE TOUR
A 405	SITY OF VERMONT MEDICAL CENTER SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST RE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)		n	SEG- ANTACHED PM of- Caical	41715

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PRINTED: 08/84/2015 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED OMB NO. 0938-0391 <u>CENTERS FOR MEDICARE & MEDICAID SERVICES</u> (X3) DATE SURVEY COMPLETED (X1) PROVIDER/SUPPLIER/GLIA (X2) MULTIPLE CONSTRUCTION STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION IDENTIFICATION NUMBER: A. BUILDING . 8. WING 470003 03/19/2015 STREET ADDRESS, CITY, STATE, ZIP CODE NAME OF PROVIDER OR SUPPLIER 111 COLCHESTER AVE UNIVERSITY OF VERMONT MEDICAL CENTER BURLINGTON, VT 05401 PROVIDER'S PLAN OF CORRECTION (BACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE COMPLETION DATE SUMMARY STATEMENT OF DEFICIENCIES (X4) ID PŘEPIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSG IDENTIFYING INFORMATION) PREFIX TAG DEFICIENCY) A 405 Continued From page 17 A 405 had not provided any direction regarding the case. The VP of Nursing also stated the practice related to medications is "... you draw up what the order is and that is what is expected..." of nurses. Per hospital policy intravenous Medications; Preparation and Administration of : by RNs and LPNs published on 7/29/14 states * 3. A RN will administer medications via IV pueh as ordered by a physician and dispensed by the pharmacy." A 490 482.26 PHARMACEUTICAL SERVICES A 490 The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmapy directed by a registered pharmacist or a drug storage area 410-115 under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service. This CONDITION is not met as evidenced by: The Condition of Participaton: Pharmacy Services was not met due to the fallure of Pharmeny Services to act in a timely manner to ensure patient safety by replacing high dose vials of Ketamine within all applicable and high risk areas throughout the hospital. Refer to Tag A - 0500 482.25(b) DELIVERY OF DRUGS A 600 A 500 444115 in order to provide patient safety, drugs and blologicals must be controlled and distributed in

FORM CMS-8567(02-02) Previous Vortions Obsariote

accordance with applicable standards of practice,

consistent with Federal and State law.

Event JD:DHZ611

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CENTER	8 FOR MEDICARE	AND HUMAN SERVICES & MEDICAID SERVICES	19401				0938-039 GURVEY
STATEMENT OF DEFICIENCIES (X1) PROVIDER/BUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SUFFYEY COMPLETED C		
	:	470003	B. WING			03/19/2015	
	ROVIDER OR SUPPLIER SITY OF VERMONT M	edical center		11	REET ADDRESS, OITY, STATE, ZIP GODE 1 COLCHESTER AVE URLINGTON, VT 05401		
(XA) ID PREPIX TAG	かんさい つきだいだんか	STEMENT OF DEFICIENCIES Y MUST SE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF DORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCES TO THE APPROPE DEFICIENCY)	8E	COMPLETION CATE
A 500	This STANDARD Based on observa review the Pharma	is not met as evidenced by: tions, interview and record cy Services falled to act in a neuro patient safety by	A	500			,
	replacing high dost applicable and high hospital. (Patient # During an emerger MICU on 1/27/16 to ordere specific me nursing which inclineuromuscular bid muscle relaxation) Ketamine 100 mg (sedation/analgesid 45 seconds to 60 cminutes for correct (intravenously). Nat the time of admarke edministered PM followed by Ketamine of the multiple and suit sufficients and suit sufficients.	a vials of Katamina within all hirlsk areas throughout the 1) Findings Include: Int Intubation of a patient in the physician directed via verbal ideations to be prepared by used Recuronium 100mg (a boker which provides skeletal in the physician also ordered (an anesthetic agent used for seconds and duration of 10-20 at dosing of 1 to 2 mg/kg). Both ordered to be administered for ordered to be administered for ordered to MiCU, documented Recuronium 100 mg at 4:46 stamine. Although the physician mine 100 mg, amounting to 1 or or the first will of 6cc/500 mg of the physician assequently at 4:48 PM			SEG ATT ACHED. PLAM of Connection		4115
	totaling 500 mg to Resuscitation Red in cardiac arrest v (PEA) and chest t Progress Note, N 1660 - 1655 (4:50 overdose of ketar notified as well as	entire contents of the syrings patient #1. For "Adult cord", at 4:53 PM Patient #1 wavith Pulseless Electrical Activity compressions were started. Per urse #1 documents: "At approx 1-4:55 PM), realization of mine realized and MD XXXX a charge nurse." Patient #1 at cardiap drugs, however its were unsuccessfut, the Code			acity to: 47000\$ If continue		(Page 18 0

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DEPAR*	MENT OF HEALTH	AND HUMAN SERVICES & MEDICAID SERVICES			, 0	FORM /	APPROVED 0938-0391
STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA AND PLAN OF CORRECTION (DENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY . COMPLETED.		
		470003	B, WING			_	9/2016
ł .	PROVIDER ON SUPPLIER BITY OF VERMONT M	edical center		11	THEET ADDRESS, CITY, STATE, ZIP CODE IT COLCHESTER AVE URLINGTON, VT 05401		•
(X4) ID PREFIX TAG	I MARKING DESIRES NO	TEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SO IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (SACH CORRECTIVE ACTION SHOULD OROSS-REPERÈNCED TO THE APPROP DEPICIENCY)	92	(75) COMPLETION DATE
A 500	procedure efforts we pronounced dead at a pronounced dead at a procedure of Patient lesues identified dead concentration. Ketamine used by included the Result included pharmacy concentrations of it 200 mg vials and a throughout the hos safety barrier in price the prescribed. The Dinad been 48 days changes had not bing, multidose vials medication boxes, concentration. The preventing the chadren at 8:40 AM, the Riccontained Ketamin Per Interview on 3 who is the medications of pretty close to the and 20 cc vial (20 titlis never use medications of the and 20 cc vial (20 titlis never use medications of the and 20 cc vial (20 titlis never use medications of the and 20 cc vial (20 titlis never use medications of the medications of the and 20 cc vial (20 titlis never use medications of the medications of the and 20 cc vial (20 titlis never use medications of the medications of the and 20 cc vial (20 titlis never use medications of the medications of the and 20 cc vial (20 titlis never use medications of the medic	rere ended and the patient was at 5:16 PM. 18/16 at 12:50 PM, the Safety and Advocacy stated uring the RCA included the size of the multidose vial of Nurse #1. An action plan actiation Committee which is would evaluate alternative (stamine such as 100 mg or standardize the dose vial applial. This would provide a eventing a targer dose of awn and administered during a		5500	SEE ATT ALHED PLAM OF CONCESTION		419-110

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CENTE	RS FOR MEDICARE	AND HUMAN SERVICES 8. MEDICAID SERVICES 0x1) PROVIDER/SUPPLIER/CLIA	pes MULT	PLE CONSTRUCTION	FORM OMBING Joxen DA); 03/24/2016 MAPPROVED J. 0838-0391 MG BURVEY
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIES AND PLAN OF CORRECTION (X2) PROVIDER/SUPPLIES AND PLAN OF CORRECTION (X3) PROVIDER/SUPPLIES		IDENTIFICATION NUMBER:	A. BUILDIN	G	C	
		470003	B. WING			/19/2016
	PROVIDER OR BUPPLIER BITY OF VERMONT N			STREET ADDRESS, CITY, STATE, ZIP CO. 111 COLCHESTER AVE BURLINGTON, VT 05401	DB	
(III (AX) XITƏRQ BAT	SUMMARY 8T/ (BAOH DEFIGIENC REGULATORY OR U	ATEMENT OF DEFICIENCIES LUCIENCE PRESENT SET SET SET SET SET SET SET SET SET SE	ID PREFIX TAG	FROVIDER'S PLAN OF CORP (EACH CORRECTIVE ACTION S CRUSS-REFERENCED TO THE AI DEFICIENCY)	HOULO BR	(MS) COMPLETION OATE
A 600	further discussions needed pilor to ma concentration. The acknowledged program is looking at the visite right dose. Per interview on 3/Anesthesiology act Services has 2 cor mg/1 cc and 100 m provision of patien Anesthesiology statements of Ketamine 0.1 and to reduce opioid dose have access Pyxls (automated are alerts to assure Parinterview on 3/Pharmacy Manager confirmed there will be comber of 20/Index and still are availaded and still are availaded anosthesia Services. On 3/10/Manager for Clinications, or and still are availaded anosthesia Services. On 3/10/Manager for Clinications of the concentrations of	age 20 nortege of Ketamine and that with Anesthesia Services was aking any changes in Ketamine pharmacist further per medication administration and making sure you have 17/15 at 1:00 PM, the Chief of knowledged Anesthesia noentrations of Ketamine, 10 ng/1 co available for the 1 care. The Chief of the 1 care. The Chief of the 2 care. The Chief of the 3 care and years ago his/her pharmacy to provide pre-drawing, vary low doses of 0.2 mg/kg used as an adjunct only and the 100 mg/1 co in medication station) but there is the right dose is being used. 19/15 at 12:15 PM the per for Clinical Practice as drug shortage of Ketamine 100 and was resolved in 2010, her confirmed if asked in lake a change in Ketamine vial ricus drug concentrations were ble. Further confirming es already has the Pharmacy ling predawn syringes of iffic needs within Anesthesia 16 12:10 PM, the Pharmacy vials had been removed from and replaced with 200 mg	3	SCE- ATT ACHES PLAY & CONVE	J. J	4117/13

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